

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

The Comparison Between High Calorie, High Fat Diets with Different Glycemic Indexes on Some Biomarkers Related to Diabetes and Oxidative Stress in Children and Adolescents with Cystic Fibrosis

Protocol summary

Summary

The study aims to compare the effectiveness of high-calorie, high-fat diets with different glycemic index, on some indicators related to diabetes and oxidative stress in children and adolescents with cystic fibrosis. In this study, which is a double blind randomized controlled trial, study population are children and adolescents with cystic fibrosis who will come to cystic fibrosis clinic in Children Medical Center. After Cystic Fibrosis in patients was approved by pulmonologists, patients will be referred to nutrition team in order to get proper diet. After assessment for inclusion criteria, including the age range between 2-18, children and adolescents with cystic fibrosis whose disease is approved by sweat test or genetic test by the clinician, willingness to cooperate and participate in the study and not having no entry criteria like: developing other chronic diseases, severe liver disease (cirrhosis), hospitalization at baseline or one month earlier in the hospital, undergoing surgery in the next three months or a month before the start of the study (with the exception of dental surgery). Benefits and risks will be explained to parents and children explanation will be given to parents and children if they were willing to cooperate the consent form will be signed by parent or children. In second visit 10 cc of blood for biochemical tests will be taken from patients, general information and individual characteristics forms as well as dietary recall questionnaire will be filled. Indicators related to anthropometric characteristics before the intervention, including height (height gauge with accuracy of 0.5 cm), weight (by scales Seca carefully 100g) will be measured and BMI (Body Mass Index) will be calculated by formula and will be recorded in general information form. Selection of one of the two regimes was through randomization method by Stratified Randomized Block Design in terms of sex and age and patients will be entered into one of the two groups high calorie, high fat or

high calorie, high fat diet with low glycemic index (sample size of each group=21). The number of food units per serving which is written in paper, and Exchange List tab and nutritional advice and allowed foods (for Group II) will be given to each of the patients in both group. Patients will be assessed via telephone whether they adhere to their diets every two weeks within three months. The researcher will be available to answer any questions and fix problems with the regime through this time. In last visit after three months from the beginning of the intervention 10 cc of blood for biochemical assessment will be taken and height and weight and BMI of the patients after three months of intervention will be recorded in general information form.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015112825267N1**

Registration date: **2017-05-21, 1396/02/31**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-05-21, 1396/02/31

Registrant information

Name

Maryam Mahmoudi

Name of organization / entity

School of Nutritional Sciences & Dietetics, Tehran University of Medical Sciences,

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2016-09-15, 1395/06/25

Expected recruitment end date

2017-03-20, 1395/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison Between High Calorie,High Fat Diets with Different Glycemic Indexes on Some Biomarkers Related to Diabetes and Oxidative Stress in Children and Adolescents with Cystic Fibrosis

Public title

Comparison Between Two Different Diets in Children and Adolescents with Cystic Fibrosis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: children and adolescents aged 2-18; children and adolescents who affected disease is confirmed by genetic or sweat test; willingness to cooperate Exclusion criteria: unwilling to cooperate and continue; inability to pursue each types of the diet; urgent need of hospitalization during trial; urgent need of operation during trial

Age

From 2 years old to 18 years old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 42

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Ghods Street, Keshavarz Blvd

City

Tehran

Postal code

Approval date

2017-07-25, 1396/05/03

Ethics committee reference number

IR.TUMS.VCR.REC.1395.489

Health conditions studied

1

Description of health condition studied

cystic fibrosis

ICD-10 code

E84

ICD-10 code description

cystic fibrosis

Primary outcomes

1

Description

insulin

Timepoint

pre intervention and 3 months after beginning the diet

Method of measurement

ELISA Kit

2

Description

fasting blood glucose

Timepoint

pre intervention and 3 months after beginning the diet

Method of measurement

ELISA Kit

3

Description

HDL cholestrol

Timepoint

pre intervention and 3 months after beginning the diet

Method of measurement

measurement of variables blood level biochemically

4

Description

LDL cholestrol

Timepoint

pre intervention and 3 months after beginning the diet

Method of measurement

biochemical measurement

5

Description

MDA

Timepoint

pre intervention and 3 months after beginning the diet

Method of measurement

ELISA Kit

6

Description

RBP4

Timepoint

pre intervention and 3 months after beginning the diet

Method of measurement

ELISA Kit

7

Description

HbA1c

Timepoint

pre intervention and 3 months after beginning the diet

Method of measurement

ELISA Kit

8

Description

Total cholestrol

Timepoint

pre intervention and 3 months after beginning the diet

Method of measurement

biochemical measurement

Secondary outcomes

1

Description

Height

Timepoint

begining of the trial and three months after

Method of measurement

meter

2

Description

weight

Timepoint

begining of the trial and three months after

Method of measurement

Scale

Intervention groups

1

Description

Intervention group: Following High fat , High calorie diet with low gycemic index for three months

Category

Prevention

2

Description

control: Following high fat , high calorie diet for three months

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Children Medical Center Hospital

Full name of responsible person

Niloufar Arabzadegan

Street address

No 24, Rahmati-Behambari Alley, Valiasr Street, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical sciences

Full name of responsible person

Mrs. Khoshtarkib

Street address

Tehran University of Medical Sciences , Ghods Street , Keshavarz Blvd

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Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty